Complete Summary

GUIDELINE TITLE

Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. London (UK): National Institute for Clinical Excellence (NICE); 2002 Sep. 24 p. (Technology appraisal guidance; no. 47).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Acute coronary syndromes, including unstable angina, non-ST-segment-elevation myocardial infarction (NSTEMI), and myocardial infarction with ST-segment elevation (also known as STEMI)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Emergency Medicine
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide guidance on the clinical and cost-effectiveness of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes

TARGET POPULATION

Patients with acute coronary syndromes

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment of risk factors, including clinical history, clinical signs, and clinical investigations
2. Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors (abciximab, eptifibatide, or tirofiban)

MAJOR OUTCOMES CONSIDERED

- Clinical-effectiveness
    - Mortality rate
    - Rate of major adverse cardiovascular events (acute myocardial infarction (AMI)/recurrent AMI, cardiovascular death, severe recurrent angina, stroke)
    - Risk of hemorrhage
    - Other adverse events
    - Quality of life
- Cost and cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Health Economics, University of York (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Search Strategy

The following databases were searched for relevant literature (See Appendix 1 of the Assessment Report [see the "Availability of Companion Documents" field] for full details of the search strategies)

- MEDLINE (WinSPIRS, 1966-2001/06)
- PubMed (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi Searched 7 Sept 2001)
- EMBASE (WinSPIRS, 1980-2001/08)
- Conference Papers Index (Dialog, 1973-2001/Sept.)
- Cochrane Library (CD-ROM, 2001/3)
- TRIP database (http://www.tripdatabase.com/ on the 5 Sept. 2001)
- DEC reports (http://www.dh.gov.uk/PublicationsAndStatistics/Publications/fs/en on the 5 Sept. 2001)
- Health Technology Assessment (HTA) database (http://www.york.ac.uk/inst/crd on the 5 Sept. 2001)
- Database of Abstracts of Reviews of effectiveness (DARE) database (http://www.york.ac.uk/inst/crd on the 5 Sept. 2001)
- National Health Service Economic Evaluation Database (NHSEED) database (http://www.york.ac.uk/inst/crd on the 5 Sept. 2001)
- National Coordinating Centre for Health Technology Assessment (NCCHTA) website (http://www.hta.nhsweb.nhs.uk/ on the 7 Sept. 2001)
- National Guideline Clearinghouse (http://www.guideline.gov/ on the 7 Sept 2001)
- National Research Register (CD-ROM Issue 2001/3)
- ScHARR Lock's Guide to the Evidence (http://www.shef.ac.uk/scharr/ir/shevm-p.htm on the 7 Sept. 2001)
- Scottish Intercollegiate Guidelines Network (SIGN) guidelines (http://www.sign.ac.uk/index.html on the 7th Sept. 2001)

Search results were de-duplicated against previous results obtained for the HTA review and the Leeds update project. The Leeds update project is secondary research funded by the Health Technology Assessment programme, which focuses on the use of glycoprotein (GP) IIb/IIIa antagonists in non-ST elevation acute coronary syndrome (ACS) patients.

For the two clinical indications covered in the earlier rapid reviews (the acute use of GP IIb/IIIa antagonists in non-ST-elevation ACS and alongside percutaneous coronary intervention [PCI]) and for the third indication (the use of GP IIb/IIIa antagonists alongside thrombolytic therapy in acute myocardial infarction [AMI]), the searching and review period went back to the date from which the medical management review commenced (i.e., the start of CD ROM resources). See Appendix 2 of the Assessment Report [see the "Availability of Companion Documents" field] for the original search strategy.

The authors of trials identified in the National Research Register (NRR) were contacted by e-mail initially followed by a follow up telephone call, for further information about their studies. Other contacts included the Cochrane Heart Group and researchers known to have published economic analyses in the area of coronary artery diseases. Six possible relevant trials were identified. The lead person in all of the cases was contacted for more information, only one replied (Trial of abciximab, lead person Dr Rodney Foale). This trial has been discontinued due to recruitment difficulties.

The bibliographies of all included studies were reviewed to identify further relevant studies.

Any information from consultees submitting to National Institute for Health and Clinical Excellence (NICE) was also searched for relevant data, conforming to the inclusion criteria of the review.

Inclusion and Exclusion Criteria

Interventions

1. Glycoprotein IIb/IIIa antagonists: abciximab (ReoPro®); eptifibatide (Integrilin®), and tirofiban (Aggrastat®).
2. Thrombolytics: GP IIb/IIIa antagonists listed above, when used alongside one of the following thrombolytics: alteplase (Actilyse®), reteplase (Rapilysin®), streptokinase (non-proprietary), and tenecteplase (TNKase, Metalyse®).

Comparators

The direct comparator to the glycoprotein IIb/IIIa antagonists was typically placebo in all indications. Depending on the indication, patients would also typically be taking a range of standard medical treatments such as aspirin and unfractionated heparin in unstable angina. In respect of the use of glycoprotein IIb/IIIa antagonists alongside thrombolytics, thrombolytic therapy alone was the relevant comparator.

Participants

For the three patient types listed below:

1. Patients who presented with unstable angina or ACS defined as increasing angina, rest angina, new onset angina, variant angina (ST elevation), non-Q wave myocardial infarction (MI) and post-MI angina. "Acute coronary

syndrome" means any constellation of clinical signs or symptoms suggestive of AMI or unstable angina (UA) without ST elevation on resting electrocardiogram (ECG).
2. Patients who were undergoing acute or elective PCI.
3. Patients who had confirmed AMI and were undergoing thrombolytic therapy.

Outcomes

- AMI/recurrent AMI
- Cardiovascular death
- Overall mortality
- Composite outcomes
- Severe recurrent angina
- Haemorrhagic stroke
- Fatal bleeding episode
- Major bleeding episode
- Minor bleeding episode
- Revascularisation
- Other adverse events
- Quality of life
- Cost and cost-effectiveness

Study Designs

1. Randomised clinical trials
2. Subgroup analysis of previously reported trials concerning one or more recognised high-risk groups: the elderly, diabetics, patients with positive Troponins, patients with ST depression on initial ECG
3. Full economic evaluations where both cost and effects have been considered (including cost-effectiveness, cost-minimisation, cost-utility, cost-benefit, or cost-consequences analyses)

Pilot studies for other studies were excluded.

Economic Evaluation

Search Methods

The two earlier reviews of glycoproteins commissioned by NICE contained much of the relevant literature. Hence the economics studies identified in those documents were taken as the core of the literature, and an update search undertaken to take the literature up to the date relevant for the project. Search strategies are shown in Appendix 1 and 2 of the Assessment Report (see the "Availability of Companion Documents" field). These are the same search strategies used by National Health Service Centre for Reviews & Dissemination (CRD) for their earlier review of GP IIb/IIIa antagonists. Hence, the inclusion criteria for the present searches was designed not to repeat but to update the searches.

Inclusion Criteria

As detailed above, the inclusion criterion for economic studies was full economic evaluations where both cost and effects have been considered (including cost-effectiveness, cost-minimisation, cost-utility, cost-benefit, or cost-consequences analyses).

NUMBER OF SOURCE DOCUMENTS

Six economic studies and 22 efficacy papers were selected for inclusion in the review.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Centre for Health Economics, University of York (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Data Extraction Strategy

Two reviewers independently assessed all obtained titles and abstracts for inclusion. Data were extracted into tables independently by one reviewer and checked by a second. A third reviewer was consulted to resolve any discrepancies. Authors were contacted in an attempt to gather missing information.

Quality Assessment Strategy

All trials included in the review were assessed using a list of items indicating components of internal validity in a standardised fashion. This list was pre-tested on a small sample of excluded studies addressing the appraisal topic. In addition, details of treatment, patients included and outcome phenomena were recorded. Finally, more descriptive information, such as year of publication and language, was noted. The validity assessment tool can be seen in Appendix 3 of the Assessment Report (see the "Availability of Companion Documents" field).

Two reviewers independently scored the internal and external validity of each included study. Discordant scores based on obvious reading errors were corrected. Discordant scores based on real differences in interpretation were resolved through consensus. A third party was sought if necessary. The reviewers were not blinded for names of authors, institutions, journals, or the outcomes of the trials.

Synthesis and Analysis

The results of the data extraction and assessment of study validity are presented in structured tables and as a narrative description. For efficacy papers, the results are also presented as relative risk forest plots. These were intended only as a graphical representation of results. As no pooling of results was undertaken, the line of effect depicted for each study does not reflect the weight of each trial. Both beneficial and adverse events are discussed in the light of study quality.

Heterogeneity of studies has been assessed by clinical judgements of differences regarding:

- Patients enrolled
- Interventions
- Outcome phenomena
- Study quality

Economic Evaluation

Data Extraction and Quality Assessment

The data extraction tables set out in the earlier review was used to extract the majority of data from the studies. However, it was felt that, for the purposes of this project, additional information regarding sub-group analysis and methods of extrapolation was needed, so these fields were added onto the extraction tables.

All trials included in the review were assessed using a list of items indicating components of internal validity in a standardised fashion (Appendix 6 of the Assessment Report [see the "Availability of Companion Documents" field]). The checklist for economic studies is based on that used in the earlier reviews; however, some fields have been changed for ease of interpretation.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Glycoprotein (GP) IIb/IIIa Inhibitors for the Medical Management of Acute Coronary Syndromes (ACSs)

The Assessment Group found no additional cost-effectiveness studies beyond the seven included in the previous appraisal of GP IIb/IIIa inhibitors. None of these studies was United Kingdom (UK)-based. Since management of ACS in the UK differs from that in other developed countries, particularly in regard to the rate of percutaneous coronary intervention (PCI), the results were not considered to be applicable to the UK. Economic models for tirofiban and eptifibatide were submitted by the manufacturers for the original appraisal.

Use as an Adjunct to PCI

A further six economic studies in the literature were identified in addition to the 17 studies included in the original appraisal, but none of these fully reflects current UK practice and the long-term costs and consequences. The original appraisal also considered the manufacturer's submission for abciximab.

Assessment Group Model

In summary, the Assessment Report model, which is the closest representation of current UK practice available, indicates that the most cost-effective strategy is for GP IIb/IIIa inhibitors to be used as part of the initial medical management of high-risk ACS patients, irrespective of whether angiography with a view to PCI is performed. Although early angiography with a view to PCI is considered to be of benefit in the initial management of high-risk ACS patients, this was not assessed in the model and is not within the scope of the present guidance. The model suggests that the cost effectiveness of GP IIb/IIIa inhibitors is not dependent on whether a PCI is performed; therefore their administration does not need to be delayed until a decision is made to carry out PCI. The use of GP IIb/IIIa inhibitors as an adjunct during PCI only is also less cost effective than their use in initial medical management.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors should be considered part of the management pathway for unstable angina or non-ST-segment-elevation myocardial infarction (NSTEMI). This management pathway also includes other pharmacological interventions and, where appropriate, early coronary angiography with a view to revascularisation either by percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG).
- The intravenous use of a small-molecule glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitor (eptifibatide or tirofiban), in addition to aspirin and unfractionated heparin, is recommended as part of the initial medical management of patients with unstable angina or NSTEMI who are at high risk of subsequent myocardial infarction (MI) or death.
- Whilst it is recognised that early angiography is desirable for high-risk patients, in situations where PCI does not occur or is not immediately available, initial medical management with GP IIb/IIIa inhibitors is still recommended.
- It is recommended that in determining who is at high risk, clinicians should take into account combinations of risk factors such as: clinical history, including age, previous MI, and previous PCI or CABG; clinical signs, including continuing pain despite initial treatment; and clinical investigations, such as electrocardiogram (ECG) changes (particularly dynamic or unstable patterns indicating myocardial ischaemia), haemodynamic changes, and raised cardiac troponin levels (see below).
- Cardiac troponin testing is useful for diagnosing acute coronary syndromes and in risk stratification. However, it is recommended that in patients considered to be at high risk, treatment with a small-molecule GP IIb/IIIa inhibitor is initiated as soon as high-risk status is determined even though this may be before the result of a troponin test is known.
- If PCI is indicated as part of the early management of unstable angina or NSTEMI, but it is delayed beyond the initial medical management phase, then the use of a GP IIb/IIIa inhibitor is recommended as an adjunct to the PCI. (Currently only abciximab is licensed as an adjunct to PCI.)
- It is recommended that a GP IIb/IIIa inhibitor is considered as an adjunct to PCI for all patients with diabetes undergoing elective PCI, and for those patients undergoing complex procedures (for example, multi-vessel PCI, insertion of multiple stents, vein graft PCI, or PCI for bifurcation lesions); currently only abciximab is licensed as an adjunct to PCI. In procedurally uncomplicated, elective PCI, where the risk of adverse sequelae is low, use of a GP IIb/IIIa inhibitor is not recommended unless unexpected immediate complications occur.
- GP IIb/IIIa inhibitors are not currently licensed in the UK for use as an adjunct to thrombolytic therapy in ST-segment-elevation MI.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes to improve survival and decrease the risk of subsequent myocardial infarction

POTENTIAL HARMS

The side effects of all glycoprotein IIb/IIIa inhibitors (abciximab, eptifibatide, tirofiban), including bleeding and thrombocytopenia, are related to their pharmacological effects. For full details of side effects and contraindications, see the Summary of Product Characteristics, available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

For full details of side effects and contraindications for abciximab, eptifibatide, and tirofiban, see the Summaries of Product Characteristics, available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- All clinicians who treat people with an acute coronary syndrome (ACS) should review their current policies and practice in line with the guidance (see the "Major Recommendations" field).
- Local guidelines or care pathways, particularly those on the management of patients with unstable angina or myocardial infarction (MI), should incorporate the guidance (see the "Major Recommendations" field).
- To measure compliance locally with the guidance, the following criteria could be used. Further details of suggestions for audit are presented in Appendix D of the original guideline document.
    - The following groups of patients receive an intravenous small-molecule glycoprotein (GP) IIb/IIIa inhibitor (eptifibatide or tirofiban) as part of their initial medical management (together with aspirin and unfractionated heparin):
        - patients with unstable angina who are at high risk of subsequent MI or death
        - patients with non-ST-segment-elevation myocardial infarction (NSTEMI) who are at high risk of subsequent MI or death
    - Patients who are at high risk and for whom percutaneous coronary intervention (PCI) is recommended but delayed beyond the initial medical management phase receive a GP IIb/IIIa inhibitor (abciximab) as an adjunct to PCI.
    - A GP IIb/IIIa inhibitor (abciximab) is considered as an adjunct to PCI for all patients with diabetes who are undergoing elective PCI or for those patients undergoing complex procedures.
    - A GP IIb/IIIa inhibitor is not used for patients who are undergoing procedurally uncomplicated, elective single-vessel PCI, unless unexpected immediate complications occur.
- Local clinical audits on the care of patients with ACS also could include criteria on other aspects of care referred to in the National Service Framework for Coronary Heart Disease.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. London (UK): National Institute for Clinical Excellence (NICE); 2002 Sep. 24 p. (Technology appraisal guidance; no. 47).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Sep

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Sep. 1 p.

(Technology appraisal 47). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- A systematic review update of the clinical effectiveness and cost effectiveness of glycoprotein IIb/IIIa antagonists. Assessment report. NHS R&D HTA Programme; 2002 Apr 9. 204 p. Available in Portable Document Format (PDF) from the NICE Web site.
- A cost-effectiveness model comparing alternative management strategies for the use of glycoprotein IIB/IIIA antagonists in non-ST-elevation acute coronary syndrome. Modelling report. 68 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0132. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Guidance on the use of glycoprotein IIb/IIIa inhibitors in the treatment of acute coronary syndromes. Information for patients. London (UK): National Institute for Health and Clinical Excellence (NICE); 2002 Sep. 8 p. (Technology appraisal 47).

Electronic copies: Available in English and Welsh in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N0133. 11 Strand, London, WC2N 5HR.

NGC STATUS

This NGC summary was completed by ECRI on August 15, 2006.

in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk.

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